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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/230,955      | 05/04/99    | MASON                | R A-67653/DCA7      |

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BRUMBACK, B

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1642     | 10.          |


DATE MAILED: 04/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

|                                      |                                     |
|--------------------------------------|-------------------------------------|
| Application No.<br><b>09/230,955</b> | Applicant(s)<br><b>Mason et al.</b> |
| Examiner<br><b>Brenda Brumback</b>   | Art Unit<br><b>1642</b>             |



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1)  Responsive to communication(s) filed on Mar 5, 2001
- 2a)  This action is **FINAL**.
- 2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4)  Claim(s) 1-5, 7, and 8 is/are pending in the application.
  - 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) 5 and 7 is/are allowed.
- 6)  Claim(s) 1-4 and 8 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved.
- 12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- 13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - a)  All b)  Some\* c)  None of:
    - 1.  Certified copies of the priority documents have been received.
    - 2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_
    - 3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- 15)  Notice of References Cited (PTO-892)
- 16)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19)  Notice of Informal Patent Application (PTO-152)
- 20)  Other:

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### **DETAILED ACTION**

1. This action is responsive to the amendment filed 05/05/2001. Claims 6 and 9 were canceled. Claims 1-5, 7, and 8 are pending and under examination.

#### *Claim Objections*

3. The objections to claims 1-9 as lacking proper introduction and for the date of deposit of the recited cell lines and depository address are withdrawn pursuant to applicant's amendment thereof.

#### *Specification*

4. The objections to the specification as lacking an abstract and for citation of TEXAS RED® are withdrawn due to applicant's amendment thereof.

#### *Claim Rejections - 35 USC § 112/101*

5. All outstanding rejections of claims 1-9 under 35 U.S.C. 112, second paragraph, and under 35 U.S.C. 101, are withdrawn due to applicant's cancellation of claims 6 and 9, amendment of claims 1-5 and 7-8, and arguments, which were persuasive.

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6. The rejection of claims 1-9 under 35 U.S.C. 112, first paragraph, for the scope of claims drawn to determination of any abnormality is withdrawn subsequent to applicant's amendment thereof.

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

*Claim Rejections - 35 USC § 102*

8. The rejection of claims 1 and 2 under 35 U.S.C. 102(b) as being anticipated by Kerr et al. is withdrawn pursuant to applicant's amendment thereof.

The rejection of claims 1 and 2 under 35 U.S.C. 102(b) as being anticipated by any of Porta et al., Kamiya et al., or Smedts et al. is maintained. Applicant's arguments have been fully considered but they are not persuasive.

Applicant argues that none of Porta, Kamiya, or Smedts teaches the claimed method comprising contacting a panel of two or more monoclonal antibodies with a tissue sample. The examiner disagrees.

Porta teaches contacting cervical epithelium with monoclonal antibodies (in the plural; see the abstract). Absent some evidence to the contrary, the plural monoclonal antibodies of Porta are equivalent to a panel of two or more and the cervical epithelium disclosed by Porta is a tissue sample.

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Kamiya teaches contacting smears of cervical cells with a panel of three antibodies (see the abstract). The art defines "tissue" as a collection of similar cells and the intercellular substances surrounding them (see Stedman's Medical Dictionary, 24th ed., page 1456, attached hereto).

Therefore, absent some evidence to the contrary, the cervical smears taught by Kamiya constitute a cervical tissue sample, as it is defined in the art.

Smedts teaches contacting cervical tissue samples (see the paragraph bridging pages 404-405) with a panel of 5 monoclonal antibodies (see page 403, column 2, first sentence of the last partial paragraph and page 405, the paragraph bridging columns 1 and 2).

***Claim Rejections - 35 USC § 102/103***

9. The rejection of claim 4 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over any of Kerr et al., Porta et al., Kamiya et al., or Smedts et al. is withdrawn pursuant to applicant's amendment thereof and arguments, which were persuasive.

The rejection of claim 8 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over any of Kerr et al., Porta et al., Kamiya et al., or Smedts et al. is maintained. Applicant's arguments have been fully considered but they are not persuasive for the following reasons.

Applicant argues that non-specific binding mechanisms are not encompassed by the claims, due to the terms "compete" and "specific". Claim 8, however, does not recite "specific"

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competition; thus, the claim encompasses antibodies which compete for binding to cervical samples due to stearic hindrance.

***NEW GROUNDS OF REJECTION***

***Claim Rejections - 35 USC § 112***

10. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure meets the enablement requirement have been outlined in the prior Office action.

The instant disclosure fails to meet the enablement requirement for the following reasons:

*The nature of the invention:* The claimed invention is drawn to a method of determining a premalignant or neoplastic disease state in a cervical tissue sample comprising contacting a panel of two or more monoclonal antibodies with the tissue sample and comparing the pattern of binding with a pattern of binding to normal cervical cells.

*The state of the prior art and the predictability or lack thereof in the art:* While the art teaches that premalignant and neoplastic cells express cellular antigens which may be elucidated by staining with monoclonal antibodies directed against those antigens, the art also teaches that the antigens expressed in premalignant or neoplastic cells are expressed in some populations of normal cervical cells, as well (see Smedts et al. for a general discussion of the expression of one

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group of antigens in normal, premalignant, and neoplastic cells; especially the abstract, last sentence). The art also teaches that the antigens expressed in premalignant and neoplastic cells differ according to the type of disease (see for example Kamiya et al., page 133, column 2, first full paragraph), *i.e.* that the cellular antigens expressed in one type of neoplasia are not necessarily expressed in others. The art teaches that while expression of certain cellular markers is helpful in the diagnosis of premalignant and neoplastic changes, there is no specific group of specific cellular markers that is in and of itself diagnostic of a premalignant and neoplastic condition. The art teaches that expression of cellular markers is at best used in conjunction with other parameters, such as cellular morphology for example, in determining the presence of a premalignant or neoplastic condition.

*The amount of direction or guidance present and the presence or absence of working examples:* The disclosure does not teach that a premalignant or neoplastic condition can be diagnosed or determined based solely on the pattern of cellular markers as elucidated by a panel of monoclonal antibodies. Rather, the instant disclosure teaches that the panel of monoclonal antibodies is useful for flagging suspect samples for further analysis. See for example, page 48 (lines 16-21), wherein the specification teaches "Any significant variance from the established parameters indicates a need for individual diagnosis by suitably qualified personnel to assess the clinical status, ie suspect samples are highlighted using the present invention for further examination".

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*The breadth of the claims and the quantity of experimentation needed:* Because the claims are drawn to a method of determining a premalignant or neoplastic disease state in cervical tissue cells comprising contacting the cells with a panel of two or more monoclonal antibodies and comparing the pattern of binding with the pattern of binding in normal cells, and because the art teaches that such a method is at best a screen for flagging potentially premalignant or neoplastic samples, it would require undue experimentation by one of skill in the art to be able to practice the claimed invention.

#### *Conclusion*

11. Because of the new grounds of rejection herein, this action is made nonfinal.
  
12. **Claims 5 and 7 are allowable.**
  
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Brumback whose telephone number is (703) 306-3220. If the examiner can not be reached, inquiries can be directed to Supervisory Patent Examiner Anthony Caputa whose telephone number is (703) 308-3995. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Brenda Brumback, Art Unit 1642 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Art Unit 1642 FAX telephone number is (703)-305-3014. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a



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Saturday, Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

BB

April 20, 2001

  
Brenda Brumback,  
Patent Examiner